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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|--------------------------------|---------------------|------------------|
| 10/070,523 | 03/13/2003 | Monique Maria Andrea Verstegen | 294-123 PCT/US | 7211 |
| 7590 | 11/02/2005 | | EXAMINER | |
| Ronald J Baron Hoffman & Baron 6900 Jericho Turnpike Syosset, NY 11791 | | | GUZO, DAVID | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/070,523 | Applicant(s) VERSTEGEN ET AL. | |
| | Examiner David Guzo | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/5/03.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 17 and 21, drawn to a method for transducing target cells with retroviral vectors.

Group II, claim(s) 8-11, drawn to a method for producing retroviral particles at high titers.

Group III, claim(s) 12-16, drawn to a composition comprising retroviral vectors at high titers.

Group IV, claim(s) 18-19, drawn to a composition comprising transduced CD34 positive cells.

Group V, claim(s) 20 and 22, drawn to use of a composition comprising transduced CD34 positive cells in the preparation of a medicament for treatment of various hemoglobin disorders.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed invention is not novel and hence does not possess a special technical feature which distinguishes it over the art (See Hanenberg et al., Human Gene Therapy, 1997, Vol. 8, pp. 2193-2206, cited in the International Search Report).

The technical feature of Group I is a method for transducing target cells with gene delivery vehicles of retroviral origin comprising providing a selection of CD34 positive cells from a culture of cells, taking a plurality of samples of said CD34 positive population, diluting and/or concentrating said samples to provide a range of concentrations of cells per volume, contacting samples in said range with a composition comprising said gene delivery vehicles and determining the optimal concentration of target cells for efficient transduction and diluting or concentrating said CD34 positive population to said optimal concentration and contacting said population with said gene delivery vehicles to allow for said transduction of target cells. The technical feature of Group II involves an unrelated method for producing retroviral particles at high titers,

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which involves method steps which are unrelated to the steps involved in Group I. The technical feature of Group V involves the use of retroviral transduced CD34 positive cells in the preparation of a medicament for treatment of genetic hemoglobin disorders. The method of Group V involves method steps unrelated to the methodologies recited in Groups I and II and is directed to a distinct outcome. The technical feature of Group III involves high titer retroviral vector compositions while the technical feature of Group IV involves CD34 positive cells transduced with retroviral vectors. The transduced cells do not share the technical feature of Group III with regard to the high titer concentration of vectors but only recite CD34 positive cells containing one or more vectors. The compositions of Groups III and IV do not share the technical features of the method Groups I-II and V and can be made by and used in other methods distinct from the methodologies recited in Groups I-II and V.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM - 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
October 31, 2005


DAVID GUZO
PRIMARY EXAMINER